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Proposed Re-evaluation Decision

Naphthalene

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Table of Contents

Overview

What Is the Proposed Re-evaluation Decision?

After a re-evaluation of the insecticidal uses of naphthalene, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing continued registration for the sale and use of products containing naphthalene in Canada.

An evaluation of available scientific information found that pest control products containing naphthalene do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of naphthalene uses, new risk-reduction measures must be implemented for all products. Additional data are being requested as a result of this re-evaluation.

This proposal affects all pest control end-use products containing naphthalene registered in Canada. Once the final re-evaluation decision is made, the registrants will be instructed on how to address any new requirements.

This Proposed Re-evaluation Decision is a consultation document[1] that summarizes the science evaluation for naphthalene and presents the reasons for the proposed re-evaluation decision. It also proposes additional risk-reduction measures to further protect human health and the environment.

The information is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides more detailed information on the assessment of naphthalene.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (please see contact information indicated on the cover page of this document).

What Does Health Canada Consider When Making a Re-evaluation Decision?

Naphthalene as a pest control product is part of the PMRA's current pesticide re-evaluation program. This program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities.

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[1] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

Naphthalene is also used as an intermediate in industrial processes in larger volumes than those used in pesticides, and has been identified as high priority for action by Health Canada and Environment Canada under the Chemicals Management Plan. Naphthalene is included in Batch 1 of the Chemicals Management Plan and a Screening Assessment as well as a Proposed Risk Management Approach were published in July 2008. The Proposed Risk Management Approach states that pesticide uses of naphthalene will be re-evaluated by PMRA based on currently available information including the Chemicals Management Plan Screening Assessment.

In the United States, pesticide uses of naphthalene have undergone re-evaluation as part of the United States Environmental Protection Agency (USEPA) Reregistration Program, and a Reregistration Eligibility document (RED) was published in September 2008. Based on the health and environmental risk assessments published in the 2008 RED, the USEPA concluded that naphthalene was eligible for reregistration provided risk-reduction measures were adopted. The USEPA RED was found to cover the science areas that are necessary for the Canadian re-evaluation of naphthalene pest control uses, and to address all formulation types and uses of naphthalene registered in Canada.

The USEPA RED, the Canadian Chemicals Management Plan Screening Assessment and Proposed Risk Management Approach, as well as a Risk Assessment Report on naphthalene generated by the European Union in 2003 were used as a basis for the proposed Canadian re-evaluation decision.

In this decision, the PMRA has also taken into consideration the Canadian specific chemistry of registered pest control products as well as the federal Toxic Substances Management Policy (TSMP).

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

What Is Naphthalene?

When used as a pest control product, naphthalene is an insecticide in the form of mothballs or flakes for control of moth and larvae which are destructive to textiles made of natural fibres. Moth balls or flakes are to be placed by hand by home owners in airtight containers (trunk or chest) where clothing is stored. Joints or holes are to be sealed with adhesive tape to prevent loss of vapour and entry of insects. Naphthalene vapours build up to levels toxic to the adult or larvae forms of the moth.

Health Considerations

Can Approved Pest Control Uses of Naphthalene Affect Human Health?

Naphthalene is unlikely to affect your health when used according to the revised pest control product label directions.

Exposure to naphthalene could occur during placement of mothballs or flakes by homeowners, after placement from inhabiting indoor areas treated with naphthalene, and from accidental ingestion of mothballs by toddlers.

The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers).

The 2008 USEPA RED covers the aspects of human health risk assessment that are necessary for the Canadian re-evaluation of naphthalene pesticidal uses, and it addresses all naphthalene formulation types and uses registered in Canada. The USEPA concluded that naphthalene was unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

The Canadian Chemicals Management Plan Screening Assessment estimated the potential risk to the Canadian population from exposure to naphthalene based on measured concentrations in homes in Canada. Although this assessment cannot be directly related to the use of pest control products since there are multiple sources of naphthalene in homes, the overall conclusion was taken into consideration in this re-evaluation. The Screening Assessment has concluded that naphthalene may be entering the environment in a quantity that may constitute a danger to human life or health and that preventive or control actions should be developed to protect the health of Canadians and their environment from the potential effects of exposure to this substance. Additional mitigation measures are proposed in view of this conclusion.

The European Union has looked at the potential risk from use of naphthalene for the control of moths indoors and has concluded that "there is a need for limiting the risk".

The carcinogenic and non-carcinogenic potential of naphthalene resulting from inhalation exposure is currently being reassessed by the USEPA Integrated Risk Information System (IRIS) program. There is also research being conducted by industry on the pharmacokinetics of naphthalene. The PMRA may revisit the naphthalene re-evaluation assessment when the IRIS assessment and research on pharmacokinetics are completed.

Environmental Considerations

According to label directions, mothballs and flakes are to be placed exclusively indoors and no environmental exposure is expected to result from the use of naphthalene as a pest control product.

Measures to Minimize Risk

As a result of the re-evaluation of naphthalene, the PMRA is proposing further risk-reduction measures.

Human Health

- Modification of packaging to reduce the potential for accidental ingestion by toddlers.
- Reduction of application rate and modification of packaging to reduce potential release of naphthalene vapours inside homes.
- Addition of the statement "For indoor use only" on all labels to clarify that outdoor uses are not registered in Canada.
- Addition of label language to provide clearer use directions.

What Additional Scientific Information Is Required?

Data are required as a condition of continued registration under section 12 of the *Pest Control Products Act*. The registrants of this active ingredient must provide these data or an acceptable scientific rationale to the PMRA within the timeline specified in the decision letter. Appendix I lists all data requirements.

Next Steps

Before making a final re-evaluation decision on naphthalene, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will then publish a Re-evaluation Decision[2] document that will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA's response to these comments.

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2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Science Evaluation

1.0 Introduction

When used as a pest control product, naphthalene is an insecticide in the form of mothballs or flakes used to control moth and larvae which are destructive to textiles made of natural fibres.

Following the re-evaluation announcement for naphthalene, the registrant of the technical grade active ingredient in Canada indicated that they intended to provide continued support for all pesticide uses included on the labels of end-use products in Canada.

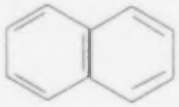
The PMRA used the Canadian 2008 Canadian Screening Assessment and Proposed Risk Management Approach, the 2008 assessments of naphthalene from the United States Environmental Protection Agency (USEPA) and a Risk Assessment Report on naphthalene generated by the European Union in 2003.

Health Canada and Environment Canada's Screening Assessment for the Challenge-Naphthalene and Proposed Risk Management Approach for Naphthalene are available on the Chemical Substances website (www.chemicalsubstances.gc.ca). The USEPA Reregistration Eligibility Decision (RED) document for naphthalene, dated 8 September 2008, as well as other information on the regulatory status of naphthalene in the United States can be found on the USEPA Pesticide Reregistration Status page (www.epa.gov/pesticides/reregistration/status.htm). The European Union Risk Assessment Report on naphthalene can be found on the European Commission, Joint Research Centre, Institute for Health and Consumer Protection website (http://ecb.jrc.it/Documents/Existing-Chemicals/RISK_ASSESSMENT/REPORT/naphthalenereport020.pdf).

2.0 The Technical Grade Active Ingredient, Its Properties and Uses

2.1 Identity of the Technical Grade Active Ingredient

Common name	Naphthalene
Function	Fumigant insecticide
Chemical family	Polycyclic aromatic hydrocarbon (PAH)
Chemical name	
1 **International Union of Pure and Applied Chemistry (IUPAC)**	Naphthalene

2	**Chemical Abstracts Service (CAS)**	Naphthalene
	CAS Registry Number	91-20-3
	Molecular formula	$C_{10}H_8$
	Structural formula	
	Molecular weight	128
	Purity of the technical grade active ingredient	99.9%
	Registration Number	21662

Based on the manufacturing process used, impurities of human health or environmental concern as identified in the *Canada Gazette*, Part II, Vol. 142, No. 13, SI/2008-67 (2008-06-25), including TSMP Track 1 substances, are not expected to be present in the product.

2.2 Physical and Chemical Properties of the Technical Grade Active Ingredient

Property	Result
Vapour pressure	6.5 Pa
Solubility in water	30 mg/L
***n*-Octanol–water partition coefficient**	Log K_{ow} = 3.3

2.3 Description of Use Pattern

Naphthalene is registered as a pest control active ingredient in the form of moth balls or flakes to control moth adult and larvae which are destructive to textiles made of natural fibres.

Moth balls or flakes are to be placed by hand in airtight containers (trunk or chest) where clothing is stored. Joints or holes are to be sealed with adhesive tape to prevent loss of vapour and entry of insects. Naphthalene has the property to sublimate, i.e. it can transition from a solid to a gas, and therefore once mothballs or flakes are placed, vapours build up to levels toxic to the adult or larvae forms of the moth. The maximum application rate is 1667 g a.i./m^3.

All current pesticide uses are being supported by the registrant(s) and were, therefore, considered in the re-evaluation of naphthalene. Appendix II lists all naphthalene products that are registered as of 22 July 2009, under the authority of the *Pest Control Products Act*.

3.0 Impact on Human Health and the Environment

3.1 Human Health

3.1.1 Health Canada/Environment Canada Risk Assessment

Naphthalene is used in various industry sectors as a chemical intermediate in volumes much larger than those of pesticides. Naphthalene is on the Canadian Domestic Substance List (DSL), an inventory of all substances manufactured in, imported into or used in Canada on a commercial scale. The *Canadian Environmental Protection Act*, 1999 (CEPA, 1999) requires the Minister of the Environment and the Minister of Health to conduct screening assessments of substances that have met the categorization criteria set out in the Act to determine whether these substances present or may present a risk to the environment or human health. Based on this exercise, naphthalene was one of approximately 200 substances that were identified as a high priority for action and was subsequently included in the Ministerial Challenge initiative of the Chemicals Management Plan. A Screening Assessment and Proposed Risk Management Approach for naphthalene were published in July 2008.

Based on estimates of intake for each age group in the general population of Canada, the Screening Assessment concluded that inhalation of indoor air is the main contributor to the overall naphthalene exposure. An upper bound estimate of indoor air naphthalene concentration was compared to concentrations at which non-cancer effects were observed in animals in toxicological studies. The upper bound indoor air concentration was estimated at 158.05 $\mu g/m^3$. This was based on a survey of homes conducted by Health Canada in Windsor between 2005 and 2006. This value was believed to generally capture emissions from consumer products and other sources such as migration of volatile organic compounds from attached garages.

It was concluded that the upper-bounding concentration of naphthalene in indoor air may approach the critical effect level for non-cancer effects of the respiratory system.

Cancer effects were addressed in a qualitative manner. It was concluded that carcinogenicity is a critical effect based on the observation of respiratory tract tumours in rodents; while the mode of action for induction of tumours has not been fully elucidated, it cannot be precluded that tumours observed involved direct interaction with genetic material.

Therefore, although uncertainties in the evaluation of the risk to human health were acknowledged, the following was concluded: On the basis of the carcinogenicity of naphthalene, for which there may be a possibility of harm at any level of exposure, as well as the potential inadequacy of the margin between the upper-bounding concentration of naphthalene in indoor air and the critical effect level for non-cancer effects, naphthalene may be entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in

Canada to human life or health. It was therefore concluded that naphthalene meets one or more of the criteria for "toxic" as defined in section 64 of CEPA.

A Proposed Risk Management Approach was published in July 2008 in which it is proposed that naphthalene, based on the results of the screening assessment, be added to the List of Toxic Substances in Schedule 1 of CEPA. An instrument describing preventive or control actions to protect the health of Canadians and the environment from the potential effects of exposure to this substance is scheduled to be published in the *Canada Gazette*, Part I, by July 2010.

3.1.2 United States Environmental Protection Agency Health Risk Assessment

The USEPA has completed a human health and ecological risk assessment of pesticide uses of naphthalene under their reregistration program. A risk management decision was published in a 2008 RED, and naphthalene was found eligible for reregistration as a pesticide provided that the recommended mitigation measures are implemented.

Registered pesticide formulations of naphthalene in the United States include moth balls, granules or flakes. As in Canada, it is used indoor in residential settings for control of cloth eating moths. However, in the United States there is also an outdoor use, around the garden or building peripheries, to repel animals such as snakes or rabbits. Indoor it is applied at a maximum rate of 494 g a.i./m^3 and outdoor at a maximum rate of 40 g a.i./m^3.

The USEPA health risk assessment included an estimate of potential risk in residential settings a) during application by homeowners (via dermal and inhalation), b) postapplication from inhabiting indoor areas previously treated with naphthalene (via inhalation), c) from episodic ingestion by toddlers, and d) via drinking water. The risk assessments were as follows.

a) During application
A quantitative assessment was conducted to estimate the risk from dermal exposure for homeowners applying naphthalene indoors and outdoors in residential settings. The estimated Margin of Exposures were greater than 100 and below the USEPA's level of concern. No inhalation endpoint was selected nor was there inhalation exposure data available to estimate handler inhalation exposure. However, the USEPA assumed that the acute postapplication inhalation assessment was protective for handler inhalation exposure.

b) Postapplication indoor
It was expected that naphthalene would volatilize and be inhaled by adults accessing treated areas (i.e. containers, dresser drawers, closets, etc) and by adults and children that inhabit treated areas. Exposure from accessing treated areas was considered to be acute in duration, exposure from inhabiting treated areas was short-, intermediate- and long-term in duration.

When levels of ambient naphthalene measured in human exposure studies were compared to no observed adverse effect levels (NOAELs) and lowest observed effect levels (LOAELs) from rodent toxicity studies, results were described by USEPA to be as follows: Acute and short-term exposure were 20× and 30× below the rodent dose resulting in no adverse effects. The

intermediate term exposure was found to be 540× below the selected NOAEL and the estimated long-term exposure was found to be 5400× below the animal dose resulting in respiratory toxicity (a LOAEL as a NOEAL could not be selected for long-term exposure duration).

Generally, unless there is evidence to the contrary, it is assumed that toxicological effects observed in laboratory animals are relevant to humans and that humans are more sensitive to effects of a chemical than the most sensitive animal species. In the case of naphthalene, inhalation toxicity studies indicate that naphthalene is a nasal toxicant in rodents at low experimental concentrations. However, according to the USEPA, research show that primates, thus humans, are less sensitive than rodents to these effects. This is potentially due to differences in the rate of bioactivation of naphthalene as well as anatomical and physiological differences in the nose and respiratory tract. These critical differences between primates and rodents were not accounted for in the USEPA assessment. Thus, with consideration of differences in dosimetry and species metabolism of naphthalene, the margins of exposure for human inhalation risk assessment were expected by USEPA to be larger than the differences calculated between the rodent NOAELs and LOAELs and the measured ambient naphthalene levels from exposure studies. Based on this, the USEPA concluded that the inhalation exposure estimates did not represent a risk of concern.

The carcinogenic and non-carcinogenic potential of naphthalene resulting from inhalation exposure is currently being reassessed by the USEPA IRIS program. When this assessment is finalized, the USEPA will determine whether the human health hazard potential of naphthalene warrants revisiting. There is also ongoing research being conducted by industry to provide additional information on species differences and pharmacokinetics of naphthalene. When this research is completed the USEPA may revisit the naphthalene inhalation risk assessment.

The USEPA also indicated that as part of the reregistration process, an additional confirmatory chamber study will be required from registrants to determine levels of naphthalene in the air resulting from the use of mothballs at the maximum rate over intermediate and long-term durations.

c) Mothball ingestion by children

Based on their incident report data, the USEPA concluded that naphthalene produces a disproportionately high number of exposure incidents when compared to the average for all other pesticides with a large proportion being incidents of children less than six years of age ingesting mothballs applied indoor. The severity of the reported incidents is much lower than for other pesticides as a whole. From a 13-year period of Poison Control Center data, approximately 7% of naphthalene incidents in children resulted in any symptoms at all, and less than 1% had moderate or major symptoms. Symptoms that did occur were not life-threatening.

The USEPA estimated the potential dose rate of a toddler ingesting one mothball, which was then compared to an oral toxicity endpoint to calculate an MOE. Toddler episodic ingestion of naphthalene mothball resulted in an MOE<1 and, therefore, was considered to be of concern. In addition, the USEPA estimated the amount of a single mothball that a toddler could ingest to result in an MOE of 100. It was found that an oral dose of 0.5 mg/kg bw/d would be required to result in an MOE of 100; which is equivalent to ingesting less than 1% of a mothball.

The USEPA concluded that the accessibility of the indoor use product to young children is of greater concern than the potential health effects, as evidenced by the large number of reported incidents, and limiting accessibility to naphthalene was expected to significantly reduce the number of incidents, including those that may result in symptoms. To that end, the USEPA determined that mothballs could no longer be marketed in such a way that individual mothballs are applied to areas accessible to children and requires that indoor products are packaged in a way that would discourage children from eating the product. Implementation in the United States is required within five years.

d) Drinking water (and Aggregate Risk Assessment)
Given naphthalene is registered for residential outdoor use in the United States, the USEPA concluded that potential exposure could result from naphthalene contaminating drinking water as a result of this use. Based on a Tier I estimate of exposure, risk estimates were all found well below the 100% reference doses for chronic and acute exposure. An aggregate risk assessment for all expected routes of exposure was not performed as no common toxicity was found among all the routes of exposure. A short-term aggregate risk assessment could have been performed by combining short-term incidental oral exposure and average background dietary (in this case drinking water) exposures. However, this was not performed for naphthalene since the short-term incidental oral exposure risk estimate alone was found to exceed the level of concern (LOC), and combining with other routes would only further exceed the LOC.

3.1.3 European Union Risk Assessment Report

The European Union has assessed potential human health and environmental risk associated with all uses of the substance naphthalene (including industrial and consumer uses) and published a report in 2003. The European Union report characterized the risk to naphthalene used as mothballs on a qualitative basis only, by comparing an estimate of inhalation and dermal exposure with toxicological endpoints identified from their database. They concluded that the highest airborne naphthalene concentration estimated from an exposure study is higher than the LOAEL for nasal olfactory effects in rats. However, they emphasized that considerable uncertainty surrounded the significance of the values used in the assessment in view of the possible substantial species differences between rats and humans for local nasal effects.

Regarding potential carcinogenicity of naphthalene, the European Union report concluded that there is uncertainty concerning the mechanism by which tumours arise in the rat and concerning the relevance of these effects to human health. However, overall, it was not possible to dismiss the rat nasal olfactory data as being of no relevance for humans.

Based on this, it was concluded that "there is a need for limiting the risk". No recommendations for mitigation measures were included in the European Union report.

3.2 Environment

3.2.1 Environmental Risk Assessment

In Canada, when used according to label directions, naphthalene is placed exclusively indoors, inside airtight containers or kept indoors for storage. This use is not likely to result in environmental exposure or exposure of non-target organisms, and therefore, an environmental risk assessment is not required.

3.3 Canadian Specific Considerations

3.3.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances (those that meet all four criteria outlined in the policy, i.e. CEPA-toxic or equivalent, predominantly anthropogenic, persistent and bio-accumulative).

According to label directions, naphthalene mothballs or flakes are used exclusively indoors in Canada and would not represent a significant source of environmental exposure. Also, naphthalene is associated with an *n*-octanol–water partition coefficient (log K_{ow}) of 3.3 which is below the TSMP Track 1 cut-off criterion of $\geq$5.0, and therefore is not expected to be bioaccumulative. Naphthalene is not a candidate for Track 1 classification.

3.3.2 Contaminants and Formulants of Health or Environmental Concern

During the re-evaluation of naphthalene, contaminants in the technical are compared against the *List of Pest control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*.[3] The list is used as described in the PMRA Notice of Intent NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act* and is based on existing policies and regulations including: Regulatory Directives DIR99-03 and DIR2006-02, *Formulants Policy and Implementation Guidance Document* and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol).

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[3] *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

Based on the manufacturing process used, impurities of human health or environmental concern as identified in the *Canada Gazette*, Part II, Vol. 142, No. 13, SI/2008-67 (2008-06-25), including TSMP Track 1 substances, are not expected to be present in the product.

3.4 Overall Conclusion

The Canadian Screening Assessment estimated the potential risk to the Canadian population from exposure to naphthalene based on measured concentrations in homes in Canada. Although this assessment cannot be directly related to the use of pest control products since there are multiple sources of naphthalene in homes, the overall conclusion should be taken into consideration in this re-evaluation. The Screening Assessment has concluded that naphthalene may be entering the environment in a quantity that may constitute a danger to human life or health and that preventive or control actions should be developed to protect the health of Canadians and their environment from the potential effects of exposure to this substance.

The European Union has looked at the potential risk from use of naphthalene for control of moth indoors and has concluded that "there is a need for limiting the risk".

The 2008 USEPA RED concluded that use of naphthalene for pest control continues to be acceptable provided that additional mitigation measures are implemented. The USEPA RED covers the main science areas, such as human health and the environment, that are necessary for the Canadian re-evaluation of naphthalene pest control uses, it addresses the active ingredient, all formulation types and uses registered in Canada. Therefore conclusions in the naphthalene RED are considered relevant to the Canadian situation.

Based on the above, naphthalene, used as a pest control product, is considered to be acceptable for continued registration with implementation of additional mitigation measures. The following is required:

- Improved packaging to mitigate the risk of accidental ingestion of mothballs by children. The registrant is required to submit a proposal for improved packaging of mothballs which would discourage children from eating the product (for example, naphthalene formulated as blocks or cakes, packaged individually in sachets). Additional label language is also required to ensure that mothballs are not applied loose to areas accessible to children.

- To clarify that outdoor uses of naphthalene mothball or flakes are not registered in Canada, the following statement should be added on the front panel of labels of Canadian products: "For indoor use only".

- In view of the concerns raised in the Canadian Screening Assessment, additional measures are required to further reduce potential inhalation exposure of homeowners by addressing the concern with overall levels of naphthalene in homes. The following is required:

1) a reduction of the maximum rate. In the United States, according to the USEPA RED, naphthalene is applied indoor at a maximum rate of 330 to 494 g a.i./m^3. This is less than the Canadian maximum application rate of 1667 g a.i./m^3. The Canadian maximum application rate for mothballs and flakes must be reduced to match that of the American rate. Further language must be added to the label to clarify use and rate instructions: guidance on the number of mothballs to be placed per type of storage space and instructions regarding the calculation of the space volume should be provided.

2) modification of the packaging of mothballs and flakes. The registrant must submit a proposal for improved packaging of mothballs and flakes which would minimize the release of vapours while naphthalene products are in storage (for example, use of a re-sealable hermetically closed container, and reduction of the number of mothballs/amount of flakes per product). The following statement must also be added to Canadian labels: "Store in a dry place, inaccessible to children and pets."

The carcinogenic and non-carcinogenic potential of naphthalene resulting from inhalation exposure is currently being reassessed by the EPA IRIS program. Research is being conducted by the Naphthalene Coalition on the pharmacokinetics of naphthalene. Based on the results of the IRIS assessment and the additional research on pharmacokinetics, the PMRA may revisit the naphthalene re-evaluation assessment.

A confirmatory chamber study is required to determine levels of naphthalene in the air resulting from use of mothballs at the maximum rate for intermediate and long-term postapplication inhalation exposure to naphthalene in residential indoor settings (section 12 of the *Pest Control Products Act*).

4.0 Incidence Reports

Since 26 April 2007, the law requires registrants to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. The PMRA examines incident reports and, where there are reasonable grounds to suggest that the health and environmental risks of the pesticide are no longer acceptable, appropriate measures are taken, ranging from minor label changes to discontinuation of the product.

There were no incident reports submitted for naphthalene as of 13 May 2009.

5.0 Organisation for Economic Co-operation and Development Status of Naphthalene

Canada is part of the Organisation for Economic Co-operation and Development (OECD), which groups 30 member countries and provides governments with a setting in which to discuss, develop and perfect economic and social policies. They compare experiences, share information and analyses, seek answers to common problems, and work to co-ordinate domestic and international policies to allow for consistency in practices across nations.

The European Union has assessed potential human health and environmental risk associated with all uses of the substance naphthalene (including industrial and consumer uses) and published a report in 2003. The European Union report characterized the risk to naphthalene used as a pest control product in residential settings and concluded that "there is a need for limiting the risk". As described above, the European Union report has been taken into consideration in the proposed Canadian re-evaluation decision.

6.0 Proposed Re-evaluation Decision

The PMRA has determined that naphthalene is acceptable for continued registration with the implementation of the proposed risk-reduction measures. These measures are required to further protect human health. The labels and packaging of Canadian end-use products must be amended as per indications in Appendix III. A submission to implement label revisions and a proposal for packaging modifications will be required within 90 days of finalization of the re-evaluation decision. The registrant of the technical grade active ingredient is required to submit data as a condition of continued registration under section 12 of the *Pest Control Products Act*. Appendix I lists data requirements.

7.0 Supporting Documentation

PMRA documents, such as Regulatory Directive DIR2001-03, and data code (DACO) tables can be found on the Pesticides and Pest Management portion of Health Canada's website at www.healthcanada.gc.ca/pmra. PMRA documents are also available through the Pest Management Information Service. Phone: 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: pmra_infoserv@hc-sc.gc.ca.

The federal TSMP is available through Environment Canada's website at www.ec.gc.ca/toxics.

Health Canada and Environment Canada's Screening Assessment for the Challenge-Naphthalene and Proposed Risk Management Approach for Naphthalene are available on the Chemical Substances website at www.chemicalsubstances.gc.ca.

The European Union Risk Assessment Report on naphthalene can be found on the European Commission, Joint Research Centre, Institute for Health and Consumer Protection website at http://ecb.jrc.it/Documents/Existing-Chemicals/RISK_ASSESSMENT/REPORT/naphthalenereport020.pdf

The USEPA RED document for naphthalene is available on the USEPA Pesticide Reregistration Status page at www.epa.gov/pesticides/reregistration/status.htm.

List of Abbreviations

µg	microgram
a.i.	active ingredient
bw	body weight
CAS	Chemical Abstracts Service
DACO	data code
g	gram(s)
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram(s)
K_{ow}	*n*-octanol–water partition coefficient
L	litre(s)
LOAEL	lowest observed adverse effect level
LOC	level of concern
m^3	metre(s) cubed
mg	milligram(s)
MOE	margin of exposure
NOAEL	no observed adverse effect level
PMRA	Pest Management Regulatory Agency
RED	Reregistration Eligibility Decision
TGAI	technical grade active ingredient
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency

Appendix I Additional Data Requirements

1) Additional chemistry data required

DACO 1.0
Title: Label
Required Data: A label revised to the nominal guarantee if this value is different from the current minimum.

DACO: 2.12.2
Title: Statement of Product Specification Form (SPSF)
Required Data: An SPSF which includes the nominal concentration (NC), lower and upper certified limits (LCL and UCL) for the active ingredient, and the NC and UCL for all the impurities present in the product above 0.1%.

DACO: 2.13.3
Title: Batch Data
Required Data: The applicant is requested to provide analytical data from five recent batches of the TGAI to 0.1% as per Section 2.13.3 of Regulatory Directive Dir98-04, *Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient or an Integrated System Product*.

2) Other data required

The USEPA is requiring a confirmatory study to determine levels of naphthalene in the air resulting from use of mothballs at the maximum rate. This is to refine estimates of intermediate and long-term postapplication inhalation exposure to naphthalene in residential indoor settings. This study is also required by the PMRA as a condition of continued registration under section 12 of the *Pest Control Products Act*.

DACO 5.6: Postapplication – Passive dosimetry data

Appendix II Registered Products Containing Naphthalene as of 22 July 2009

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee (%)
2525	Domestic	Recochem Inc.	Recochem naphthalene Moth Balls	Balls	99.9
2525.01	Domestic	Home Hardware Stores Ltd.	Naphthalene Moth Balls	Balls	99.9
6592	Domestic	Rougier Pharma Inc.	Moth balls	Balls	99.9
21662	Technical	Recochem Inc.	Naphthalene technical	NA	99.9
23770	Domestic	Recochem Inc.	Naphthalene Balls	Balls	99.9
23822	Domestic	Recochem Inc.	Naphthalene Moth Flakes	Flakes	99.9

Appendix III Additional Mitigation Measures Required for Products Containing Naphthalene

1) Packaging Amendments

A) Registrants are required to modify the packaging of end-use products to mitigate the risk of accidental ingestion of mothballs by children. Loose mothballs must no longer be sold in Canada, and registrants are required to submit a proposal for packaging/formulation options which would discourage children from eating the product (for example, naphthalene formulated as blocks or cakes, packaged individually in sachets). Additional label language is required to ensure that naphthalene products are not applied loose to areas accessible to children.

B) Registrants are required to modify the packaging of mothballs and flakes to minimize the release of vapours while naphthalene products are in storage. A proposal for packaging options must be submitted, this may include use of a re-sealable hermetically closed container, and reduction of the number of mothballs/amount of flakes per product.

2) Rate Reduction

In the United States, according to the USEPA RED, naphthalene is applied indoor at a maximum rate of 330 to 494 g a.i./m^3. This is less than the Canadian maximum application rate of 1667 g a.i./m^3. The Canadian maximum application rate for mothballs and flakes must be reduced to match that of the American rate.

3) Label Amendments

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the above label statements.

A submission to request label revisions will be required within 90 days of finalization of the re-evaluation decision.

The labels of end-use products in Canada must be amended to include the following statements to further protect human health.

a) The following statements must be included on the primary panel of all labels.

"For indoor use only"

b) The following statements must be included in a section entitled **DIRECTIONS FOR USE**.

"For use in airtight containers only. Do not use as an animal repellent."

"Apply product at the following rates:

Number of mothballs:	Enclosed space:
ADD NUMBER	Large Trunk (add volume HERE)
according to new application rate	Small drawer (add volume HERE)
	Large drawer (add volume HERE)

"The volume of the storage container to be treated can be calculated by multiplying the height, width, and depth of the space."

"Open in a well ventilated area and reseal carefully after application"

"Store in a dry place, inaccessible to children and pets."

References

Studies considered in the Chemistry Assessment

List Of Studies/Information Submitted By Registrant

PMRA Document Number: 1631533.
Reference: Part Chemistry, Data Code: 2.1,2.10,2.11,2.12,2.13,2.14, 2.2,2.3, 2.4,2.5,2.6, 2.7,2.8,2.9.

PMRA Document Number: 1631544
Reference: Technical Naphthalene, Data Code: : 2.99